

R E M A R K S

Claims 1 to 5, 7 and 8 as set forth in Appendix I of this paper are now pending in this case. Claim 6 has been canceled, and Claims 7 and 8 have been added.

Claims 7 and 8 have been added to further bring out the physical properties of the plastic mixture in accordance with applicants' disclosure on page 4, indicated lines 9 to 15, of the application, and page 5, indicated lines 16 to 18, of the application. No new matter has been added.

Withdrawal of the Examiner's rejection of Claim 6 under Sections 102(b) and 103(a) is solicited in light of applicants' cancellation of Claim 6.

The Examiner has rejected Claims 1 to 5 under Section 103(a) as being unpatentable in light of the teaching of *Klimesch et al.* (US 4,880,585) when taken in view of the disclosure of *Krismanth et al.* (US 2001/0001670), in view of the disclosure of *Wolfe et al.* (US 5,049,333), or in view of the disclosure of *Marsalka et al.* (WO 97/36722).

The teaching of *Klimesch et al.* relates to a process wherein an extrudable pharmaceutical mixture is shaped continuously by pressing the deformable extrudate between two rolls which are rotated in opposite directions and each of which have depressions opposite to each other.

In contrast to the teaching of *Klimesch et al.*, applicants' process employs for forming the pharmaceutical dosage form a system of two counter rotating rolls wherein one of the rolls has at least one annular groove running along its periphery, and the other roll has at least one ring of teeth running along its periphery, which teeth extend radially outward and are able to engage in the annular groove.

The Examiner contends that a person of ordinary skill in the art would have modified the teaching of *Klimesch et al.* as necessary to arrive at applicants' process in view of the disclosure of either one of the secondary references.

However, all of the secondary references applied by the Examiner relate to machines and methods for producing briquets by compacting

particulate materials such as charcoal. As such, the machines and methods described by the secondary references are not subject to the same stringent requirements concerning precision with regard to shape, composition, and weight which are applied in the pharmaceutical field when dosage forms of active ingredients are concerned. Precision with regard to shape, composition, and weight are utterly essential in the manufacture of dosage forms of pharmaceutically active ingredients to ensure that each of the resulting shaped articles provide for the same amount of active ingredient. It is immediately apparent that the precision which is required when materials such as charcoal are shaped to briquets is nowhere near to the precision which is necessary in the pharmaceutical art. From the standpoint of the art regarding dosage forms for pharmaceuticals, the manufacture of briquets of materials such as charcoal is therefore not sufficiently analogous to be considered by a person of ordinary skill in the pertinent art.

In order to qualify as a basis for rejection of a claimed invention, the reference must either be in the field of the applicant's endeavor or it must be reasonably pertinent to the particular problem with which the inventor is concerned<sup>1</sup>). The secondary references applied by the Examiner are clearly not within applicants' field of endeavor. The secondary references are also not reasonably pertinent to the problems confronted by applicants because they are not concerned with the high degree of precision which is necessary in the manufacture of dosage forms for pharmaceuticals.

It is therefore respectfully requested that the Examiner favorable reconsider her position and withdraw the rejection under Section 103(a) based on the teaching of *Klimesch et al.* when taken in view of the disclosure of *Krismanth et al.*, or the disclosure of *Wolfe et al.*, or the disclosure of *Marsalka et al.* Favorable action is solicited.

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1) In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (CAFC 1992), see also In re Deminski, 796 F.2d 436, 230 USPQ 313 (CAFC 1986); In re Clay, 966 F.2d 656, 23 USPQ2d 1058 (CAFC 1992); and Wang Laboratories Inc. v. Toshiba Corp., 993 F.2d 858, 26 USPQ2d 1767 (CAFC 1993).

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OZ0480/01200

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Respectfully submitted,

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Encl.: THE LISTING OF CLAIMS (Appendix I)

HBK/BAS